

### **REMARKS**

Applicants attorney wishes to thank Examiners Lambkin and McKane for their courtesies in granting telephone interviews to discuss the outstanding rejection under 35 USC 112, first paragraph. In response to the discussion with the Examiners, Applicants have amended claim 47.

#### **Status of the claims**

With entry of this amendment claims 1-48 are pending. Claim 47 has been amended. The Examiner has allowed claims 1-46 and 48.

Claim 47 has been amended by (1) deleting the phrases "or preventing" and "or prevention" and inserting the phrase "or reducing the risk of acquiring"; and (2) by replacing the term "including" with the phrase "selected from the group consisting of." The inserted language finds support from page 14, lines 22-23 of the specification. Accordingly, no new matter is added by this amendment.

#### **Response to Office Action**

The Examiner rejects claim 47 under 35 U.S.C. §112, first paragraph, as lacking enablement for the treatment of all of the diseases recited in claim 47, or for the prevention of any of the diseases recited in claim 47. The Examiner also finds the word "including" in claim 47 indefinite. The applicants' amendments to claim 47 render these enablement and indefiniteness rejections moot.

The Examiner further rejects claim 47 under 35 U.S.C. §112, first paragraph, as lacking enablement for the treatment of all of the diseases recited in claim 47.

The applicants respectfully traverse.

The compounds of claims 1 and 29 are prodrugs of propofol. Propofol has known efficacy in treating migraine headache pain (page 2, lines 8-11), nausea and vomiting (page 2, lines 14-24), and seizures and convulsions (page 1, lines 18-25). More typically, propofol is used to induce and maintain anesthesia and/or sedation (page 1, lines 18-25) and hence its use to treat anxiety is readily appreciated (page 56, line 21 to page 57, line 12). Propofol also has antioxidant effects in humans, and because antioxidants are

known to be effective in treating certain neurodegenerative diseases, propofol is also expected to be effective in treating neurodegenerative diseases such as Friedrich's disease, Parkinson's disease, Alzheimer's disease, amyotrophic lateral sclerosis, multiple sclerosis, and Pick's disease (page 2, line 32 to page 3, line 10). The compounds recited in applicants' claims are propofol prodrugs, which following administration to a patient, release propofol in the systemic circulation (*see e.g.*, page 4, lines 1-3). Accordingly, because propofol is known to be efficacious in treating the diseases recited in applicants' claim 47, it follows that the propofol prodrugs recited in applicants' claims are also able to treat the recited diseases.


Sufficient enablement does not require that the applicants provide detailed formulation and dosage parameters. Rather it suffices "that one skilled in the art based on knowledge of compounds having similar physiological or biological activity, would be able to discern an appropriate dosage or method of use without undue experimentation." *MPEP* § 2164.01(c) (page 2100-194 Rev. 3, August 2005). Thus, based on the known methods of using propofol to treat the diseases recited in claim 47, one skilled in the art would be able to similarly employ applicants' propofol prodrugs without undue experimentation, for example by administering a prodrug of propofol to a patient in need of such treatment in a therapeutically effective dose equivalent of propofol. Furthermore, on pages 56 to 58 of the specification, the applicants disclose examples of therapeutically effective dosage ranges for treating each of the diseases recited in claim 47. Because the applicants have enabled at least one use of the propofol prodrugs recited in claim 47 the multiple uses of the propofol prodrugs of claim 1 to treat the diseases recited in claim 47 are likewise enabled (See *MPEP* § 2164.01(c) (page 2100-195 Rev. 3, August 2005).

### **Conclusion**

In view of the foregoing amendments and remarks applicants respectfully submit that the claim 47 satisfies the enablement requirement of 35 U.S.C. § 112, first paragraph and the indefiniteness requirement of 35 U.S.C. § 112, second paragraph. The applicants therefore respectfully request the Examiner's reconsideration of claim 47 and the timely allowance of all claims.

The Examiner is invited to contact the undersigned if it is believed that prosecution of this application may be assisted thereby. If there is any fee due in connection with the filing of this response, please charge the fee to our Deposit Account No. 50-2319.

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